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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,952	12/06/2000	Amit Gal-on	1268-107	7377

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ART UNIT	PAPER NUMBER
1638	13

DATE MAILED: 01/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/647,952	GAL-ON, AMIT	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *8,9,13,14 and 16-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 10-12, 15 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's restriction election, Paper No. 10, filed 11 October 2002. Applicant elects Group I, claims 1-7, 10-12, 15 and 20, with traverse, stating that all the groups are related. Applicant's traversal is unpersuasive for the following reasons: The groups lack the same or corresponding special technical feature, as stated in the last office action. Furthermore, Group II claims have different and additional features from Group I, Group III is a method of producing viral protection, Group IV is a method of producing virus, and Group V is a product, and examination would require additional search. Claims 1-20 are pending. Claims 8, 9, 13, 14, and 16-19 are nonelected. Claims 1-7, 10-12, 15 and 20 are examined in the instant application. This restriction is made FINAL.

Sequence Listing

2. Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 2 is attached to the instant Office action.

Claim Rejections - 35 USC § 112, second paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-7, 10-12, 15 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

- Claims 1-7, 10-12, and 20 recite a "substitution", which is indefinite because there is no reference given for the substitution. What is the sequence number, or amino acid name and number, of the original which is changed in the substitution? Also, is the "substitution" a nucleic acid or an amino acid?
- Claim 15 recites "a full length clone as defined in claim 11", but claim 11 does not define a full length clone.
- Claim 20 recites "collecting the results progeny" is unclear. What is the progeny of?

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, first paragraph-written description

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 7 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 7 and 10 are drawn to ZYMV-AG1, which is described as having certain sites substituted, but which is not described by a nucleic acid sequence or a SEQ ID NO, or by an accession number, or by any other means that would allow the public to practice Applicant's invention. To render such a description meaningful, the wild-type sequence of the relevant virus or gene must be given as a reference point.

Claim Rejections - 35 USC § 112-enablement

7. Claims 1-7, 10, 12, 15 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 7 and 10 are drawn to ZYMV-AG1, a specific virus. The specification lacks sufficient evidence that the claimed biological material, ZYMV-AG1, is either 1) reproducible, 2) known and readily available to the public, or 3) deposited in compliance with 37 C.F.R. 1.801-1.809. If the claimed biological material were deposited under the provisions of the Budapest Treaty, Applicant must provide a declaration stating that the claimed biological material was made under the provisions of the Budapest Treaty in compliance with 37 CFR 1.801-1.809, and that all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably

removed upon the granting of the patent. Applicant's attention is directed to 37 C.F.R. §§ 1.801-1.809, M.P.E.P. §§ 2402-2411.05 and In re Lundak, 773 F.2d. 1216, 227 U.S.P.Q. 90 (Fed. Cir. 1985) for further information concerning the Rules and Regulations for Deposit of Biological Materials for Patent Purposes.

The claims are drawn to a recombinant potyvirus infectious nucleic acid construct useful for plant cross protection, comprising a full length clone having its HC-Pro gene conserved FRNK box sequence containing a substitution, where the substitution is of an Arginine, where Arg is substituted with a hydrophobic amino acid or an amino acid having a bulky side chain, where the Arg is substituted with an Ile, where the potyvirus is ZYMV, and where the potyvirus is ZYMV-AG1. The claims are also drawn to recombinant constructs useful for plant cross protection against severe strains of ZYMV, where the construct has a sequence of DNA or RNA inserted anywhere into the full-length clone, constructs with substitutions abolishing aphid transmissibility. Also claimed are a methods for introducing foreign nucleic acid into plants using such constructs, methods for providing protection against viral infection, compositions comprising such constructs, and produce inoculated with such compositions.

Claim 1 is drawn to "a recombinant potyvirus infectious nucleic acid construct useful for plant cross protection, characterized only in that its HC-Pro gene conserved FRNK box sequence contains a substitution." This substitution can be any substitution, and any or all the four amino acids can be substituted. Applicant teaches an isoleucine substitution for an arginine, but lacks a showing of criticality for any of the other amino acids. Because the claim recites "characterized only in that its HC-Pro gene", this encompasses substitutions in other amino acids; so that any or all the remaining amino acids can vary. While one skilled in the art can readily make substitutions of amino acids, doing so without guidance as to what amino acids are critical for function, and in

what sequence, would require random trial and error experimentation. And without guidance as to how to eliminate inoperable embodiments, this would be undue experimentation, since there is not a reasonable expectation of success.

However, the specification only teaches a ZYMV-AG1 recombinant construct and the use of ZYMV-AG1 in cross protection of squash and melons against severe strains of ZYMV.

The claims are drawn to "substitution"(s). Substitutions encompass exchanging one thing for another thing, and in the instant case, the "things" being exchanged are not specified. They can be nucleic acids or amino acids. Changes in the nucleic acids of a coding sequence do not necessarily result in changes in the amino acid encoded; this is because some changes in the nucleic acids are "silent" at the amino acid level. For example, the amino acid leucine is coded by any one of six different codons; any change in the nucleic acid codon which changes the nucleic acid from one of the six leucine codons to another of the leucine codons, would be silent at the amino acid level. Though of course, the DNA would be changed. See Goodenough (Genetics. 2nd edition, 1978, Holt Rinehart, NY, pages 322-325).

Given the unpredictability, the lack of guidance-especially re "substitution", the state of the art, and the breadth of the claims (any recombinant potyvirus, cross protection of any plant, and any substitution) undue experimentation would be required to enable the invention as commensurate in scope with the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

nearly connected, to make and use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 11, 12,15 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Huet, et al. (Mutations in the helper component protease gene of zucchini yellow mosaic virus affect its ability to mediate aphid transmissibility. J. General Virology, vol 75, 1994, pages 1407-1414).

Huet teaches a recombinant potyvirus infectious nucleic acid construct comprising a full length clone having its HC-Pro conserved FRNK box containing a substitution (Figure 1, p 1408, details the full length clone of ZYMV-HC with a FRNK box substitution), where the substitution is of Ile for Arg (Table 2, p 1410), where the potyvirus is ZYMV, where the nucleic acid is a cDNA (Figure 1, page 1408, 1st line of legend), and a recombinant potyvirus PPV (p1410, Figure 2). Huet further teaches a recombinant construct where the full length clone has a sequence of DNA or RNA inserted into the full length clone (Figure 1, pg 1408, line 3 of legend, detailing the T7 promoter insertion), a method for introducing a foreign nucleic acid into plants by

infecting a plant with a full length clone (p1409, last paragraph), and using the recited nucleic acid construct to inoculate plants and obtain progeny virus (Table 1, p 1410, and Table 2, p 1411).

Accordingly, Huet anticipates the claimed invention.

Remarks

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD
Patent Examiner
Art Unit 1638 – Transgenic Plants.
December 27, 2002

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600